IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN *ex rel.* Cathleen Forney *Plaintiffs* v. MEDTRONIC, INC. *Defendant*.	Civil Action No. 15-cv-6264

RELATOR FORNEY'S SUPPLEMENTAL MEMORANDUM IN OPPOSITION TO MEDTRONIC'S MOTION FOR SUMMARY JUDGMENT

Relator Forney provided the Government with material information about Medtronic's fraudulent kickback scheme that has not been publicly disclosed in either the *Onwezen* or *Schroeder* complaints. As explained in detail below, Relator Forney, an insider in Medtronic management, was able to disclose to the Government the names of many Medtronic staff (including herself and other high-level management) involved in Medtronic's fraudulent payment of kickbacks. She was able to disclose the dates and locations when Medtronic paid the kickbacks (both in the form of device checks and consulting services), and, in some instances, identify the recipients of the kickbacks. In addition, Relator Forney provided material information that painted the full picture of

how Medtronic management knowingly and intentionally embarked on a scheme to train Medtronic sales staff to view the payment of kickbacks as the most important and valuable part of their jobs. Medtronic evaluated and compensated Medtronic sales staff in ways that financially incented sales staff to promote constantly the kickbacks ("services") to physicians and hospitals.

None of this material information about Medtronic's fraudulent scheme was disclosed in the *Onwezen* and *Schroder* complaints. Relator Forney clearly qualifies as an original source under the post-PPACA public disclosure bar who disclosed material information about 'the who, what, when, where and how of the events at issue." *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 307 (3rd Cir. 2016). Relator respectfully urges this Court to deny Medtronic's meritless motion for summary judgment, and convene the parties for a scheduling conference to set a new date for trial and new dates for completion of discovery.

PROCEDURAL BACKGROUND

By Order dated April 3, 2018 (Dkt. No. 74), the Court held that the *Schroeder* and *Onwezen* complaints constituted relevant public disclosures about Medtronic's payment of kickbacks under the post-PPACA public disclosure bar. Medtronic settled those lawsuits by paying the United States $23.5 million. The United States' press release announcing Medtronic's sizeable payment explained, "[p]atients who rely on their healthcare providers to implant vital medical devices expect that those decisions will be made with the patients' best interests in mind. ***Kickbacks, like those alleged here, distort sound medical judgments with financial incentives paid for by the taxpayers***." (Emphasis added.) Dkt. 69-10.

As a result of this holding, the Court ordered Relator to file a supplemental memorandum explaining how the information she provided to the Government "adds in a significant way to the essential factual background [set forth in the *Onwezen* and *Schroeder* complaints]: 'the who, what, when, where and how of the events at issue." *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 307 (3rd Cir. 2016). This Memorandum responds to the Court's Order, and explains the evidentiary support for Relator's status as an original source under the post-PPACA public disclosure bar.

ARGUMENT

Relator Forney alleged that Medtronic paid kickbacks in the form of free device checks and consulting services. Although Medtronic earlier argued to the Court that Relator's theory of liability was nonsensical and novel, Medtronic's own motion for summary judgment revealed the contrary: Medtronic has been sued repeatedly for paying kickbacks in the form of free services. Two of those lawsuits have been deemed eligible as "prior public disclosures" by this Court. Dkt. 74. Section I summarizes the Anti-Kickback statute's history, and explains what material details were disclosed by the *Onwezen* and *Schroeder* complaints.

As explained below in Section II.A, Relator Forney provided material evidence to the Government regarding the dates, locations, and names of involved parties (both Medtronic representatives and the participating physicians) that cannot be found in the two relevant complaints, *Onwezen* (filed as Dkt. 64-9) and *Schroeder* (filed as Dkt. 64-13). In addition, as explained below in Section II.B, Relator Forney provided new material about how Medtronic implemented the kickback scheme, and what Medtronic

gained financially from implementing the kickback scheme. As a result, it is clear that Relator Forney qualifies as an "original source" under the controlling Third Circuit *Moore* case.

I. Medtronic Has Been Sued Repeatedly for Paying Kickbacks in the Form of Services.

Congress passed the Anti-Kickback Statute[1] in 1972 to reduce unnecessary governmental health care payments. *See* Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). By 1977, however, Congress had determined that the statute was not deterring the harmful conduct. As explained in H.R. Rep. No. 95-393 (II), 95th Cong. 1st Sess. 1977, 1977 U.S.C.C.A.N. 3039, 1977 WL 16075 (Leg. Hist.),

> "The disclosures to date have focused on a broad range of improper activities which are not restricted to one class of providers or treatment settings. In whatever form it is found, however, fraud in these health care financing programs adversely impacts on all Americans. It cheats taxpayers who must ultimately be the financial burden of misuse of funds in any government-sponsored program. It diverts from those most in need, the nation's elderly and poor, scant program dollars that were intended to provide vitally needed qualify health care services. The wasting of program funds through fraud also further erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs. In addition to these adverse financial consequences, the activities of those who seek to defraud these programs unfairly call into question and [sic] honesty and integrity of the vast majority of practitioners and health care institutions. Fraud and abuse can occur in a number of different medical settings. Recent investigations have demonstrated the pervasiveness of the problems."

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[1] *See* 42 U.S.C. § 1320a-7b, stating in relevant part:
(b) Illegal remunerations (2) Whoever knowingly and willfully offers or ***pays any remuneration*** (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or ***in kind*** to any person to induce such person— **(B)** ***to purchase***, lease, order, or arrange for or recommend purchasing, leasing, or ordering ***any good***, facility, service, or item ***for which payment may be made in whole or in part under a Federal health care program***, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
Id. (emphasis added.)

Id. at 44.

As a result, Congress passed amendments, now codified in 42 U.S.C. § 1395(h), that increased the deterrence level and eliminated the ambiguities. Specifically, the amendments upgraded the crime to a felony and expanded the reach of the prohibition to include "any remuneration." *Id*. Congress specifically cited providing administrative services as one form of fraud. *See id*. at 3048. Congress also expressly broadened the scope of the statute, using the term "any remuneration" to encompass not only cash payments but also in kind payments, such as providing services as a form of bribery. 42 U.S.C. § 1395(h). Medtronic's motion for summary judgment revealed that Medtronic's cardiac division has been sued repeatedly for paying kickbacks to cardiac health care providers. Dkt. 64.

The two lawsuits in which the Government intervened were found by the Court to qualify as "public disclosures." Dkt. 74. In *Onwezen*, several Relators alleged that Medtronic paid kickbacks by bribing the physicians with free services. Dkt. 64-9. Relator Onwezen served as a Clinical Specialist until her resignation due to ethical concerns in January 2006. Co-relator Bennett was employed by Medtronic's competitor Boston Scientific in 2006, and co-relator Brill was employed by Medtronic until November 2005. The complaint provides the details available to them, including an allegation that Medtronic paid Representatives $100 for every doctor or clinic that granted Medtronic autonomy over performing device checks and billing. *See* Dkt. 64-9, Paragraph 77. Relators, however, did not include in their complaint any details regarding the actual payment of the free device check kickbacks, such as names of Medtronic

representatives providing the free services, names of physicians, locations where the free services were performed, and dates of such services.

In *Schroeder*, Relator Schroeder alleged Medtronic paid kickbacks based on his personal knowledge obtained by working for Medtronic from May 2006 until July 2007. Relator alleged Medtronic paid all sorts of kickbacks to cardiac health care providers, including sporting event tickets, visits to strip clubs, alcohol, free meals, and cash payments. Relator Schroeder provided dates of the payments for many of the kickbacks, and also the names of the receiving parties, for numerous kickbacks paid by Medtronic's cardiac division in 2006 and early 2007. In addition, Relator Schroeder also alleged Medtronic had Dr. Eric Prystowsky present a problematic medical education presentation on July 22, 2008.

As has not been disputed in any way by Medtronic, Relator Forney was unaware of the *Onwezen* and *Schroeder* complaints until Medtronic filed it with the Court on November 17, 2017. *See* Dkt. No. 69; Ex. 16 at ¶ 2. Yet the existence of the *Onwezen* complaint corroborates Relator's claim that Medtronic acted intentionally with full knowledge that its conduct was wrongful. Medtronic paid to settle the *Onwezen* complaint, so clearly it must have read the complaint, which alleges the same theory of liability that Relator alleges with respect to the free device check services. Yet Medtronic's cardiac division continued to engage in the very same misconduct, and indeed likely continues to engage. Tellingly, Medtronic's Answer reveals that despite the prior $23.5 million settlement, the company did not obtain any legal advice that might arguably insulate itself from liability for the ongoing misconduct. That is, Medtronic did

not include "an advice of counsel" affirmative defense as one of the twenty-five different affirmative defenses plead by Medtronic. *See* Dkt. 57.

II. Relator Forney Disclosed to the Government Significant New Information About Medtronic's Extensive Wrongdoing.

Given the Court's ruling that the *Onwezen* and *Schroeder* complaints qualify as statutory public disclosures, the Court needs to rule on whether Relator Forney provided material information not disclosed in those two complaints. *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 307 (3rd Cir. 2016). In *Moore*, the Third Circuit turned to Rule 9(b) standard for help in assessing materiality. The Court held, "[i]n our view, this standard also serves as a helpful benchmark for measuring "materially adds." Specifically, a relator materially adds to the publicly disclosed allegation or transaction of fraud when it contributes information, distinct from what was publicly disclosed, that adds in a significant way to the essential factual background: "the who, what, when, where and how of the events at issue." *Id*. at 307. Based on that analytical approach, in *Moore*, the Court reversed the district court, finding that relator Moore was an original source because he contributed "significant, specific details that were not publicly disclosed. . ." *Id*.

Here, Relator Forney materially added to the information about Medtronic's pattern of misconduct described in the two prior public disclosures. As explained in Sections A and B, Relator Forney disclosed to the Government a treasure trove of material information about the details regarding Medtronic's actual payment of kickbacks, as well as material information about Medtronic's use of its training, evaluation, and compensation programs to implement the kickback scheme. This

detailed information is memorialized in the documents provided to the Court. See Dkt. 69, Ex. 17.

A. Who/When/Where: Relator Provided The Government Material Information About Participants, Dates And Locations That Cannot Be Found in the Public Disclosures.

Relator Forney, a member of Medtronic management, provided the Government with material evidence about the identity of Medtronic participants who paid the kickbacks, as well as the dates and locations where the kickbacks were provided. Relator Forney also provided the Government with the names of kickback recipients. None of this detailed material information about kickbacks paid by Medtronic years after the *Onwezen* and *Schroeder* relators left Medtronic was disclosed by those relators in their complaints. Compare Ex. 17 examples memorialized below to Dkt. 64-9 and Dkt. 64-13.

1. The Dates, Locations, and Recipients of Medtronic's Kickbacks

Relator Forney alleges that Medtronic intentionally and knowingly paid kickbacks to physicians and hospitals. Medtronic did so by deploying a sales force consisting of Sales Representatives and Clinical Specialists to doctors' offices and hospitals to perform a clinical examination of implanted devices. As was well known to Medtronic, its conduct of a clinical exam allowed health care providers to bill the Government in two ways: first, for the "professional" component involved in reviewing the report generated as part of the clinical examination, and second, for the "technical" component, namely the actual clinical examination being done by the Medtronic employee. Thus, the more device checks performed for free by Medtronic's cardiac division, the more health care providers could bill the Government.

Relator Forney provided reams of material information about the specifics of Medtronic's kickbacks. The following provides extensive examples of the new material information contained in the documents. Patient initials are used rather than full names for reasons of patient privacy.

Ex. 17, REL-02254:

- on December 2, 2011, Medtronic representative Chuck Mertz conducted a device clinic from 1pm to 3:15pm at the Quakertown location for 11 patients
- on December 6, Medtronic representative Chuck Mertz conducted a device check clinic from 1pm to 3:15pm at Windgap location for 10 patients
- on January 3, 2012, Medtronic representative Chuck Mertz conducted a device clinic from 1pm to 3:15pm at the Windgap location for 10 patients
- on January 6, 2012, Medtronic representative Chuck Mertz conducted a device clinic from 1pm to 2:45pm at Quakertown for 8 patients,
- on February 3, 2012, Medtronic representative Chuck Mertz conducted device checks at Quakertown for four patients ML (1pm), HK (1:15pm), PB (1:30pm)and LE (1:45pm) (Note, the patients are identified by full name in the document.)
- on February 7, Medtronic representative Chuck Mertz conducted a device clinic from 1pm to 3:15pm at Windgap for 10 patients
- on February 27, 2012, Medtronic representative Chuck Mertz conducted a device check at 1pm at Quakertown for RT (Patient identified by full name in the document.)

Ex. 17, REL-02257-02258:

- on November 16, 2011, Medtronic representative conducted a device clinic at the Palmerton location from 1pm to 2:45pm for 8 patients, two of whom scheduled at the last minute
- on November 30, 2011, Medtronic representative conducted a device check at the Palmerton location for LE at 1:15pm, for MH at 1:30pm, for JM at 1:45pm, for MH at 2pm, and for BB at 2:15 pm (Patients identified by full name in the document.)
- on December 21, 2011, Medtronic representative conducted a device clinic at the Palmerton location for 7 patients
- on January 11, 2012, Medtronic representative conducted a device check at the Palmerton location for MG at 1pm, for WG at 1:15pm, for ES at 1:30pm, and for DW at 1:45pm. (Patients identified by full name in the document.)
- on February 15, 2011, Medtronic representative conducted a device check ath the Palmerton location for EL at 1pm, for SK at 1:15pm and for JK at 1:30pm.

Ex. 17, REL-02257-02258:

- on November 10, 2011, Medtronic representative conducted a device check at Miners location for NM at 1pm(Patients identified by full name in the document.)
- on December 8, 2011, Medtronic representative conducted a device check at Miners location for GW at 1pm, for LB at 1:30pm and for KH at 2pm. KH was a last minute addition to the schedule. (Patients identified by full name in the document.)

Ex. 17, REL-02274 establishes that Medtronic representative Marla Lyon conducted a device check (referred to as an "interrogation") for patient EH on November 29, 2011, and emailed the report to Denise Chuck of Medtronic.

See also Ex. 17, REL-02264, REL-02270 and 02272, which establish Marla Lyon provided free services at St. Luke's as well.

Ex. 17, REL-02265 establishes that Medtronic Rachel Sicilion provided free services at the Bethlehem Campus of St. Luke's on November 11, 2011.

Ex. 17, REL00682-83 reveals names of another involved in the kickbacks, Richard Conklin, Principal Clinical Specialist.

Ex. 17, REL 01418-58 provides additional material information about the names of Medtronic representatives paying the kickbacks, and the names of the health care providers receiving the kickbacks.[2] Here are a few examples drawn from that collection.

Ex. 17, REL-01419, shows Cathy Jo Leiby conducting a single device check at 10am in the Hamilton location.

[2] Ex. 17, REL-01249- 1417 reveals a significant number of identities, dates and locations of the implant surgeries where Medtronic provided free surgical services. As noted in prior pleadings, Relator Forney made a strategic decision to streamline her case, and has opted not to pursue this category of kickback at trial.

Ex. 17, REL-01421, shows Chuck Merz conducting a pacer check on November 11, 2011, at 11:30 am in the Muhlenberg location.

Ex. 17, REL-01422, shows Cathy Jo Leiby conducting a single device check for a patient in room 450 at the St. Luke's Allentown location.

Ex. 17, REL-01424/REL-01429 shows Mary Cliff and Rachel LNU conducting a device check at Country Meadows 4025 Green Pond Rd.

Ex. 17, REL-01426 shows Mary Cliff and Chuck Merz conducting a device check on Dec. 13, 2011 at 2:40pm in the Allentown location.

Ex. 17, REL-01446 shows Maria Lyons conducting a device check on November 29 for patient EH.

Ex. 17, REL-01449 is a data sheet reflecting a device check conducted by Marla Lyons on November 28, 2011.

Ex. 17, REL-01451 shows Chuck Merz conducting a device check on November 22, 2011 at 11:30am.

In addition, Relator Forney produced REL-01459-01772, a collection of scheduling calendars that Medtronic kept on Google calendar.[3] Each page of this set of documents has a particular appointment that is blown up on the page. In this way, it is possible to page through the calendars, and see the time and date of the device checks. Thus, for example, Ex. 17, REL-01466 shows an device check scheduled for October 5,

[3] Using Google to maintain device check schedules with patient names violated HIPPPA, yet Medtronic was slow to remedy this known violation. Note, although Relator is not asserting a separate cause of action arising from the HIPPPA violations, those violations are additional evidence establishing Medtronic's overall lack of adherence to the law. Medtronic eventually switched to a HIPPPA-compliant calendaring product called SalesForce. The Court allowed Medtronic to withhold production of these SalesForce calendars until after the Court's ruling on the pending motion.

2011 from 8:30 to 9:30 am at RHggs #404. Ex. 17, REL-01476 shows a device check scheduled for noon to 1pm on Wednesday, October 12, 2011 at 2030 Trevertown Rd, Shamokin for a patient RS. Ex. 17, REL-01492 shows a device check scheduled on January 24, 2011 at 11am at 100 Community Dr., Tobyhanna, for a patient. Ex. 17, REL-01548 shows a device check scheduled for October 31, 2011 at the Lundin location for a patient JK.

In addition to showing individual device checks, Relator Forney disclosed material information about how Medtronic ran "clinics" – namely, a Medtronic representative showed up in a health care providers' location for a set number of hours, during which he or she conducted one device check after another for patients. Ex. 17, REL-021682 shows Medtronic representative conducted a device check clinic for one hour at the Barnes location on January 16, 2012. Ex. 17, REL-01682 shows that Medtronic representative conducted a device clinic from 1pm to 3pm at the Fried location. Ex. 17, REL-01683-686 show details about 17 additional device clinics conducted by Medtronic.

These are but a few examples of the hundreds of names, dates and locations for the payment of kickbacks that were disclosed by Relator Forney.[4] Relator Forney disclosed material new information about which Medtronic employees were involved in Medtronic's cardiac kickback scheme. See REL-02411 and REL-02422-33, which

[4] This Memorandum contextualizes the evidence and provides the Court with extensive examples of the types of material details provided by Relator rather than exhaustively listing each and every material detail disclosed by Relator. An exhaustive list of each and every new details on "who, what, when, where and how" would run far more than 50 pages. Relator reserves her right to use all the material evidence contained in Ex. 17 at the trial of this matter even if not expressly mentioned here.

reveals the identities of many more Medtronic employees, none of whom is identified in the *Onwezen* or *Schroeder* complaints. Compare Dkt. 64-9 and Dkt. 64-13.

All of this serves as corroborating material evidence to support Relator Forney's allegations that Medtronic engaged in a fraudulent scheme to pay health care providers kickbacks in the form of free device check services. None of this material information may be found in the *Onwezen* or *Schroeder* complaints.

2. Identities of Additional Medtronic Employees Involved in Medtronic's Consulting Services Kickback Scheme

Relator Forney also disclosed material new information to the Government about the identities of persons involved in Medtronic's consulting services kickback scheme. She disclosed the identities of the "lean sigma" consultants, who were providing free consulting services to health care providers. See Ex. 17, REL-01773-87. And Relator Forney disclosed to the Government the type of "lean sigma" consulting service provided free to referral sources. See Ex. 17, REL-01773-87 (identities of staff providing the free services, descriptions of services), REL-00471-484 (worksheets created for free by Medtronic), REL-00485-491 (data collected to provide lean sigma services); REL-00492-508 (worksheets created for free by Medtronic); REL-00513-521; and REL-00494-503 (consulting given to St. Lukes). Relator Forney also provided the Government with copies of the very documents necessary to facilitate the fraudulent scheme, such as hospital credentialing agreements. See Ex. 17, REL-02512-14, REL-02515-17, REL-02520, REL-02991.

Relator Forney disclosed to the Government the names of top management involved in the kickback scheme (Dave Roberts, Tom Conlin and Pat Brown) and the categories of

management involved (namely District Managers, District Service Managers, Regional Sales Directors, and Operation Team Managers). See Ex. 17, REL-02292-95.

B. What and How: Relator Forney Provided The Government With Material Evidence About What and How Medtronic Implemented Its Fraudulent Scheme That Cannot Be Found in the Public Disclosures.

Relator Forney, a member of Medtronic management, provided the Government with significant new material evidence about how Medtronic implemented its fraudulent kickback schemes on both the device checks and consulting services. Medtronic's fraudulent scheme arose because Medtronic management knew that they would not be able to retain its majority market share if forced to compete against competitors on quality and price, which are permissible ways for a manufacturer to market products covered by Medicare reimbursement. Medtronic's competitors all had products that customers viewed as of equal quality. Ex. 17, REL-02152 reveals that Medtronic knew the cardiac products had become commodity products ("Pervasive lack of perceived differentiation"). Yet Medtronic was not willing to compete on price, and taught its sales staff to claim that it was a mistake to consider price in making the buying decisions. See Ex. 17, REL-01964, telling representatives to tell health care providers about the "disadvantages of focusing on price when making decisions about medical devices."

Medtronic could not compete on quality (which it calls "product differentiation") and was unwilling to compete on price, yet it simultaneously wanted to expand its market share. *See* Ex. 17, REL-02152, stating "Medtronic CRDM needs to defend and grow its 50 percent market share against potentially more formidable and nimble competitors – Boston Scientific and St. Jude – as well as enhance its service strengths."

Instead of competing on price (which would lower health care costs) or quality (which would raise health care quality), Medtronic opted to compete on "service." But Medtronic did not use this term to refer to delivering the cardiac products more quickly or otherwise improving "service" in a legally permissible manner. Instead, Medtronic's cardiac division ignored the Anti-Kickback statute and kept buying brand loyalty by giving physicians and hospitals an enormous quantity of free services that helped their bottom lines. Medtronic's constant appeal to the pecuniary interests of physicians and hospitals (rather than to their medical judgments) is exactly the type of conduct that the Anti-Kickback statute was designed to prevent, as it raises health care costs without improving health care quality.

Physicians were persuaded to use Medtronic products not because the products were either better or cheaper, but rather because Medtronic Clinical Specialists conducted device checks without any compensation. Given that the physician makes money from the Government for each device check performed (professional reading and technical component), the more device checks, the more money for the physician practice. And in addition to the free device checks, Medtronic taught its cardiac sales force to create ways to infiltrate physician practices by providing free consulting services, including consulting with the physicians about how their practices could make more money by billing for more device checks.

Relator Forney disclosed to the Government that Medtronic's cardiac division implemented this unlawful scheme by expressly training Clinical Specialists and Sales Representatives how to persuade physicians that working with Medtronic created financial "value" for their practices. *See* Exhibit 17, REL-02016-02037 (Value Based

Service Pre-Reading); REL-01915-2015 (Value Based Selling 1 Role Play Workbook) and REL-02038-2145 (Value Based Service Participant Workbook). Indeed, Relator Forney provided material evidence that Medtronic viewed the free services as the most important element of sales. See Ex. 17, REL-01788-812, at 798, stating "Sell the superiority of the entire CRT solution" with "service" as the top bullet point of what was being sold.

The following are excerpts of the language found in these documents that reveal how Medtronic taught its cardiac sales force (Sales Representatives and Clinical Specialists) to focus on the pecuniary interests of physicians and hospitals.

Ex. 17, REL-02022
"How many clinicians do you have on staff?" "How do you monitor your heart failure patients." "It is important that the customer view Situation Questions as an attempt on the part of the CS' part to better under his or her situation, not as a demand for information."

Ex. 17, REL-02024
"Situation Questions are useful for . . . Obtaining background information about the customer's business." "Problem Questions are essential for uncovering Implied Needs. They enable the CS to . . . develop a detailed understand of the customer's problem – Who? Which? When?

Ex. 17, REL-02026
"What sort of consequences does that lead to? Does this problem increase your costs?" "As a result of well-focused Implication Questions, the customer sees the problem as more important, and hence becomes more committed to finding a solution." "**Make Implication Questions sound natural**." (emphasis in original)

Ex. 17, REL-02028
"Would it be useful to increase the speed of this operation by 10 percent? If we could improve the quality of this operation, how would that help you?"

Ex. 17, REL-02162
"Best in class Clinical Specialists are not passive or reactive. They do not allow themselves to be carried along in the wake of a customer's innate buying process."

Ex. 17, REL-02164
"I worry that our clinic is not operating as efficiently as it could."

"Gas costs are killing us and our patients can't afford to come and see us."

Ex. 17, REL-02167
"Does this problem increase your costs?"

Ex. 17, REL-02176
"Does this lack of control adversely affect costs?

Ex. 17, REL-02178
"Does that mean you can't meet your targets? What effect does that have on scheduling? Does that lead to bottlenecks in other areas?"

Ex. 17, REL-02185
Instructs the representatives to encourage customers to state the financial benefits of working with Medtronic: "Wouldn't this led to savings? How much would you save? Is it important for your department to reduce year-to-year costs?

Ex. 17, REL-02218 "Working with the nurses and the office manager, the CS sets up a service schedule, helps educate patients and oversees inservice for staff. . . Today, the CS is the in the clinic doing device checks and talking with the office manager."

Ex. 17, REL-02219
"Office time could be filling with patient checks, each of which comes with a stack of paperwork, involving lots of time. There might not be any room to take on more patients because of this. The no-shows are a challenge too, since the office is unable to bill for the visits, and it is often too late to schedule another patient instead."

"the more time the physicians spent on patients checks, the less time they can spend in the OR, implanting new devices. And you imagine that this frustrates the doctors. In fact, the office might be losing out on opportunities to take in more revenue or to grow.

Ex. 17, REL-02245
"If we could increase your productivity by 10%, would you do business with us?"
"Wouldn't this lead to savings? How much would you save?"
Medtronic cautions its staff, "If asked too soon, Need-payoff Questions arouse suspicion and pressure customers."

Ex. 17, REL-01940
"Finally, you want to discuss the possible disadvantages of a smaller vendor. Smaller providers not only have fewer service professionals . . . The lab might run into more service-related issues, which increases lab time and costs. The cath lab manager could have to spend time finding ancillary help and appeasing the doctors. . . Having to pay overtime could also negatively affect the lab's budget."

"You are aware that the hospital's emphasis on cost control could put Medtronic at a disadvantage."

Medtronic engaged in a series of role playing exercises that make clear the Clinical Specialists and Sales Representatives were taught about the linkage between the kickbacks and the resulting "loyalty" to Medtronic products. Indeed, they were taught to threaten physicians that they might "miss out" on such free services if they altered their buying behavior. Below are a few examples from the role playing exercises created by Medtronic.

Ex. 17, REL-01922
"Dr. Byrd has always been a loyal Medtronic customer: history, Medtronic has received roughly 90 percent of the doctor's business. This represents roughly $8 million in annual revenue. Dr. Byrd has served on the Medtronic advisory committee and is routinely tapped as a speaker for medical conferences."

"In addition, Dr. Byrd might miss out an valuable capabilities Medtronic offers."

Ex. 17, REL01946
"The more time Dr. Byrd and the staff spend doing the checks, the less time there is to grow the business."

Ex. 17, REL-01951
"Dr. Drake is also failing to take advantage of Medtronic's capabilities and resources. . . By not taking advantage of external expertise in marketing, for example, the doctor have to develop their own marketing plan and materials."

Relator Forney also disclosed additional material evidence establishing that Medtronic designed its evaluation and compensation structure in a fashion that persuaded Clinical Specialists and Sales Representatives to participate wholeheartedly in paying the service kickbacks. Ex. 17, REL-01236-48 reveals that Medtronic evaluated its Clinical Specialists on whether they were able to "translate customer needs into Medtronic solutions." Medtronic designed its compensation structure to incent Clinical Specialists and Sales Representatives to offer kickbacks in the form of free services. See Ex. 17, REL-02412-421 (compensation plan); REL-00590-608 (compensation plan); REL -

00609-641(compensation plan); REL -00642-45 (sales contest); and REL -00646-51 (compensation plan.) Ex. 17, REL-01872-01887 is an example of an internal Medtronic document that corroborates Relator Forney's allegations that Medtronic sales representatives persuade physicians to buy more Medtronic products by appealing to the physicians' pecuniary interests in greater reimbursement rather than by appealing to sound medical judgment. The document shows that "Clinical Specialist" is really simply another name for a Medtronic's sales representatives. Medtronic offers prizes ("John and Ann's sexy ipad") to the representatives who sell the most REVEAL implants (insertable cardiac monitors). REL-01874.

Medtronic representatives did not appeal to the sound medical judgment of the physicians. Instead, Medtronic directed them to pitch "Reveal Reimbursement" as a topic of discussion (REL-01878), and show physicians how much money they will make if they increase the number of REVEAL devices. REL-01880-01883. This same document disclosed the Medicare Program pays for device checks for REVEAL using CPT code 93298 and 93299, at 2010 rates of $38 for technical, and $29 for professional.

Relator Forney also disclosed how Medtronic provided advice on coding. This advice included information about how much money a health care provider could make by billing for the professional and technical components of device checks. See Ex. 17, REL-00001-110 (codes for device monitoring); REL-00111-133 (physician coding); REL-00270-328 (hospital coding); REL-00329-351 (physician coding); REL-00352-406 (physician coding); REL-02437-511. And Relator Forney disclosed that Medtronic routinely encouraged physicians to contact Medtronic for billing assistance. *See, e.g.,* Ex. 17, REL-00406. Tellingly, Medtronic also taught its employees to deliver the free device

checks only when a physician was present in the office suite, which permitted the physician's office to claim the "direct supervision" element of reimbursement had been met. Ex. 17, REL—01169. If Medtronic's free services were unrelated to making more Medicare money for the physicians, they would not have designed them to match the reimbursement requirements. Yet the documents that Relator Forney gave to the Government make clear that Medtronic ***never*** cautioned physicians and hospitals to refrain from billing for the free device checks being provided by Medtronic Clinical Specialists or Sales Representatives. See Ex. 17, REL-00001-110 (codes for device monitoring); REL-00111-133 (physician coding); REL-00270-328 (hospital coding); REL-00329-351 (physician coding); REL-00352-406 (physician coding); REL-02437-511.

Medtronic also internally briefed its own employees about coding, telling them they had to understand how the physicians made money. Ex. 17, REL-01161-235. Ex. 17, REL-00397 reveals that every implant generates $29,002 to $35,878 for the physician. Medtronic even admitted internally that the Government calculated the Medicare reimbursement for the "technical component" based on "the resources using in furnishing the service, such as office rent, wages to personnel, and other office practice expenses." Ex. 17, REL-01168. Medtronic's payment of kickbacks to health care providers eliminated any "wages to personnel" – instead, health care providers were bribed by Medtronic, who offered them extensive free labor that undergirded their billings to the Medicare program for the professional and technical components of the device checks. Relator Forney also disclosed new material information about the

financial impact of Medtronic's misconduct. Ex. 17, REL-02393-410 reveals the revenue generated for Medtronic by a single hospital.

In short, Relator Forney provided the Government with material evidence revealing significant details about the "what" and "how" of Medtronic's kickback scheme that had not been revealed by the prior public disclosures. Medtronic's illegal payment of kickbacks in the form of device checks and consulting services was implemented by a Medtronic sales force that was trained and incented to appeal to the pecuniary interests of health care providers. Such kickbacks in the form of free services greatly harms the Medicare program, as it caused the submission of hundreds of thousands of fraudulent reimbursement claims, and led health care providers to remain loyal purchasers of Medtronic devices without regard to price or quality.

CONCLUSION

In conclusion, Relator Forney disclosed material "significant, specific details that were not publicly disclosed . . .." *Id*. at 307. Relator Forney provided a treasure trove of new material details not disclosed in the two relevant complaints. All of the material information provided by Relator Forney revealed the "who, what, where, when and how" of Medtronic's fraudulent scheme to buy brand loyalty in exchange for providing free device checks and consulting services. *United States ex rel. Moore & Company, P.A. v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 307 (3rd Cir. 2016) (discussing the need to disclose material information about "the who, what, when, where and how of the events at issue.") Relator Forney's material information gained from her years working as Medtronic management indisputably "improves the quality" of the kickback case against Medtronic. *United States ex rel. Moore*, 812 F.3d 294 at 306. Relator Forney

respectfully urges this Court to deny Medtronic's motion for summary judgment, and hold a status conference to set new discovery deadlines and a new trial date.

Respectfully submitted by:

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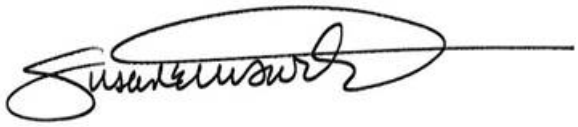

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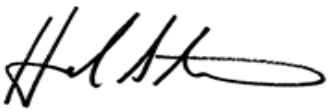

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